

CERTIFIED MAIL

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INTERNATIONAL

January 16, 2001

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00N-1678 – Expansion of Medical Device Industry Initiatives

Dear Sir or Madam:

We commend you for the expansion device industry initiatives pilot program, which has been successful in improving industry/agency communication and decreasing adversarial and confrontational situations during and following facility inspections.

We disagree, however, with the decision to discontinue post – inspection notification letters for the following reasons.

1. The post-inspection notification letters are written by either the District Director or District Compliance Director, and usually include a positive statement about the facility's state of compliance with the Federal Food, Drug, and Cosmetic Act and implementing regulations.

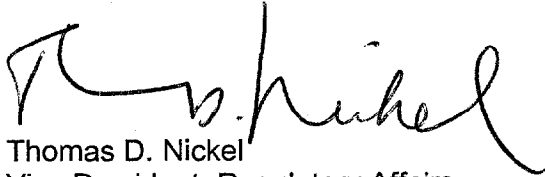
This plain-English statement from FDA District senior management is a very positive, unambiguous communication which is appreciated by the senior management of the company receiving it. Frequently the letter is circulated to the company senior managers, and is available for review by Ministry of Health officials in the few countries which require proof of compliance with FDA regulations as a condition of approval for import of devices into their country.

2. The EIR is a somewhat arcane document, written by the FDA investigator who performed the facility inspection, and frequently in a manner that does not allow an untrained reader to understand the state of compliance of the facility. In fact, the EIR may note specific nonconformance deficiencies, but no bottom line conclusion if a form FDA 483 is issued, because the investigator is only documenting what happened during the actual inspection. All subsequent company/FDA interactions and FDA conclusions are not integrated into the EIR, and not documented for the public except in the post-inspection letter which is being eliminated.

00N-1678

We realize post-inspection notification letters require resources which perhaps appear to FDA to be better utilized elsewhere, but urge you to continue sending these worthwhile and valued (by industry) expressions of goodwill.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. Nickel', written in a cursive style.

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

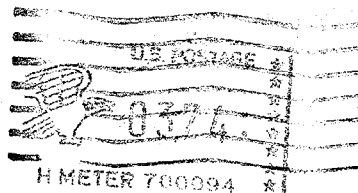
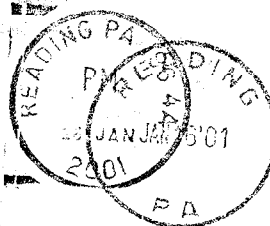
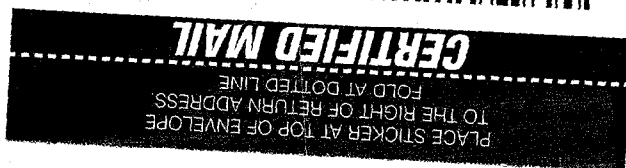
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